Wollo University

College of Natural and Computation Sciences

Department of Biotechnology

A Course Guide for Pharmacutical Biotechnology

I. General Information

A COURSE GUIDE FOR Pharmaceutical Biotechnology	COURSE TITLE: Pharmaceutical Biotechnology
MODULE NAME : Medical Biotechnology	COURSE CODE : Biot3112
MODULE CODE : Biot M3111	COURSE ECTS : 5
MODULE NUMBER: 11	COURSE WEIGHT : 0.3
ATEGORY OF MODULE: CORE	Instructor's Contact Information: ----------
MODULE ECTS: 15	E-mail:
YEAR : III	Phone
SEMESTER : II	Office Hours **Course Logistics** Location: Classroom ----, Lecture Hall------
TARGET GROUP : THIRD **YEAR BIOTECHNOLOGY STUDENTS**	

II. Teaching Method and Assessment

Summary of Teaching Learning Methods:	**Summary of Assessment Methods:**
Brain Storming	Assignments
Lecture And Gap Lecture Method	Final-exam
Buzz Group Discussion	Students
Cooperative Learning	Performance on class work and homework
Discussion	Students
Self Reflection	self-reflection

III. Students Workload

CONTACT HOURS	EFFECTIVE LECTURS HOURS	DISCUSSION	HOME BASED ACTIVITIES	LIBRARY WORK	ASSESSMENT	TOTAL
4	4x12= 64HRS	22 HRS	24HRS	21HRS	20HRS	135 HRS

IV. Course Description

The course deals with introduction of pharmaceutical biotechnology, different sources of biopharmaceuticals, production process: upstream process downstream process, product analysis, different biopharmaceutical products, interferons, intluekins, growth factors, therapeutic hormones, recombinant blood products therapeutic enzymes, vaccines and adjuvant, therapeutic antibodies, somatic gene therapy and cell/tissue based therapy, xenotransplantation, pharmacokinetics and pharmacodynamics of biopharmaceuticals.

Course Objectives At end of this course, the students will be able to:

- ✓Explain the basic processes and steps involved in the production of biopharmaceutical drugs.
- ✓ Identify the sources of varies biopharmaceutical products along with their advantage and disadvantage
- ✓Describe the method of production of varies biopharmaceutical drugs
- ✓List the application of varies pharmaceutical products
- ✓Appreciate the recent developments in molecular biology and genetic engineering and the applications in respect to biopharmaceutical industry

V. Course Assignments

- Review of about:
- The importance of Genetic Engineering.
- Recombinant DNA technology
- Types of Vector
- Transformation

- cDNA synthesis
- Applications of rDNA technology in Medicine,
- Applications of rDNA technology in Agriculture
- Applications of Gene cloning and DNA analysis in Forensic Science.

VI. Assessment Arrangements and Grading

Test 1 ……10%,
Test 2 …… 15%
Assignment1 ……10%
Mid examination……..25% and
Final Examination…….40%

VII. Course Policies

a) Ground Rules

The course is delivered based on the rules and regulations of the university and the following rules must be kept for classroom purpose

- Attending all class is **a must**
- Punctuality in class and assignment is mandatory
- Active participation is required at most
- Misbehaving at class is highly forbidden
- Disabling a cellular phone is **a must**

b) Academic honesty policy

Students are responsible for their work only. Students who cheat on exams, by whatever method, or guilty of plagiarism will, or may be given an" F" for course and dismissed permanently from class.

c) Late work

Students may take any missed exam by the consent of the department members. And students are expected to provide their evidence for missing exam since 5 days after the onset of the exam.

d) Disclaimer

This syllabus represent a best plan for the course ,but ,as with most plans, it is subject to changes made necessary by time ,space and personal constraints as the course progresses.

VIII. Required Text Books and Materials

References:

- ✓ Gary wilsh (2000). Pharmacutical biotechnology-concepts and applications
- ✓ Kayser and Muller (2000).pharmaceutical biotechnology-drug discovery and clinical application

IX. Course content

Day	Contents	Reference Materials
1	**Introduction** ✓ Historical overview ✓ Pharmaceutical biotechnology and pharmaceutical products ✓ Sources of pharmaceutical products	Gary wilsh (2000) Kayser and Muller (2000).
2	**Animal cell culture system** ✓ Animal cell culture system ✓ Insect cell based system ✓ Transgenic animals ✓ Transgenic plants products	Gary wilsh (2000) Kayser and Muller (2000).
3	**Production process** ✓ Upstream process Cell banking system : Microbial cell fermentation Mammalian cell culture system process ✓ Down stream processing Cell production and initial product concentration Filtration methods Final product formulation	
4	**Product analysis** ✓ Detection of protein based contaminants ✓ Detection of endotoxins and other pyrogenic contaminates ✓ Microbial and viral contaminants ✓ Miscellaneous contaminants	Gary wilsh (2000) Kayser and Muller (2000).

5	**Biopharmaceutical products Cytokines and growth factors** ✓ interleukins ✓ Interferons ✓ Growth factors	Gary wilsh (2000) Kayser and Muller (2000).
6	**Biopharmaceutical products** ✓ Insulin ✓ Glucagon ✓ Human growth hormone ✓ The gondaterophines ✓ Additional recombinant hormones	Gary wilsh (2000) Kayser and Muller (2000).
7	**Biopharmaceutical products Recombinant blood products** ✓ Factor VIII ✓ Factor IX, IIVa and XIII ✓ Anticoagulants ✓ Thrombolytic agents	Gary wilsh (2000) Kayser and Muller (2000).
8	**Biopharmaceutical products Therapeutic enzymes** ✓ Asparaginase ✓ DNase ✓ Debring agentws ✓ Digestive aids	Gary wilsh (2000) Kayser and Muller (2000).
9	B**iopharmaceutical products** ✓ Vaccine and adjuvant ✓ Antibodies	Gary wilsh (2000) Kayser and Muller (2000).

10	**Somatic gene therapy and cell/tissue based therapy** ✓ Viral vectors used in gene therapy ✓ Non viral vectors ✓ Gene therapy and genetic disease ✓ Stem cell therapy	Gary wilsh (2000) Kayser and Muller (2000).
11	**Xenotransplantation** ✓ Role of pharmaceutical biotechnology in tissue transplantation ✓ HLA typing	Gary wilsh (2000) Kayser and Muller (2000).
12	**Pharmacokinetics and pharmacodynamics** ✓ Protein pharmacokinetics ✓ Tailoring of pharmacokinetics profile ✓ Protein mode of action and pharmacodynamics	Gary wilsh (2000) Kayser and Muller (2000).

Approval Section

Course Instructor

Name	Date	Signature

Faculty Dean

Name	Date	Signature

Department Head

Name	Date	Signature